

Prevention, United States Department of Health and Human Services.

(l) *Non-radiogenic cancer* means a type of cancer that HHS has found not to be caused by radiation, for the purposes of this regulation.

(m) *Primary cancer* means a cancer defined by the original body site at which the cancer was incurred, prior to any spread (metastasis) to other sites in the body.

(n) *Probability of causation* means the probability or likelihood that a cancer was caused by radiation exposure incurred by a covered employee in the performance of duty. In statistical terms, it is the cancer risk attributable to radiation exposure divided by the sum of the baseline cancer risk (the risk to the general population) plus the cancer risk attributable to the radiation exposure.

(o) *RadioEpidemiological Tables* means tables that allow computation of the probability of causation for various cancers associated with a defined exposure to radiation, after accounting for factors such as age at exposure, age at diagnosis, and time since exposure.

(p) *Relative biological effectiveness (RBE)* means a factor applied to a risk model to account for differences between the amount of cancer effect produced by different forms of radiation. For purposes of EEOICPA, the RBE is considered equivalent to the radiation weighting factor.

(q) *Risk model* means a mathematical model used under EEOICPA to estimate a specific probability of causation using information on radiation dose, cancer type, and personal data (e.g., gender, smoking history).

(r) *Secondary site* means a body site to which a primary cancer has spread (metastasized).

(s) *Specified cancer* is a term defined in § 7384(l)(17) of EEOICPA and 20 CFR 30.5(dd) that specifies types of cancer that, pursuant to 20 CFR part 30, may qualify a member of the Special Exposure Cohort for compensation. It includes leukemia (other than chronic lymphocytic leukemia), multiple myeloma, non-Hodgkin's lymphoma, renal cancers, and cancers of the lung (other than carcinoma in situ diagnosed at autopsy), thyroid, male breast, female breast, esophagus, stom-

ach, pharynx, small intestine, pancreas, bile ducts, gall bladder, salivary gland, urinary bladder, brain, colon, ovary, liver (not associated with cirrhosis or hepatitis B), and bone.

(t) *Uncertainty* is a term used in this rule to describe the lack of precision of a given estimate, the extent of which depends upon the amount and quality of the evidence or data available.

(u) *Uncertainty distribution* is a statistical term meaning a range of discrete or continuous values arrayed around a central estimate, where each value is assigned a probability of being correct.

(v) *Upper 99 percent confidence interval* is a term used in EEOICPA to mean credibility limit, the probability of causation estimate determined at the 99th percentile of the range of uncertainty around the central estimate of probability of causation.

Subpart C—Data Required To Estimate Probability of Causation

§ 81.5 Use of personal and medical information.

Determining probability of causation may require the use of the following personal and medical information provided to DOL by claimants under DOL regulations 20 CFR part 30:

- (a) Year of birth
- (b) Cancer diagnosis (by ICD-9 code) for primary and secondary cancers
- (c) Date of cancer diagnosis
- (d) Gender
- (e) Race/ethnicity (if the claim is for skin cancer or a secondary cancer for which skin cancer is a likely primary cancer)
- (f) Smoking history (if the claim is for lung cancer or a secondary cancer for which lung cancer is a likely primary cancer)

§ 81.6 Use of radiation dose information.

Determining probability of causation will require the use of radiation dose information provided to DOL by the National Institute for Occupational Safety and Health (NIOSH) under HHS regulations 42 CFR part 82. This information will include annual dose estimates for each year in which a dose was incurred, together with uncertainty distributions associated with

each dose estimate. Dose estimates will be distinguished by type of radiation (low linear energy transfer (LET), protons, neutrons, alpha, low-energy x-ray) and by dose rate (acute or chronic) for external and internal radiation dose.

Subpart D—Requirements for Risk Models Used To Estimate Probability of Causation

§ 81.10 Use of cancer risk assessment models in NIOSH IREP.

(a) The risk models used to estimate probability of causation for covered employees under EEOICPA will be based on risk models updated from the 1985 NIH Radioepidemiological Tables. These 1985 tables were developed from analyses of cancer mortality risk among the Japanese atomic bomb survivor cohort. The National Cancer Institute (NCI) and Centers for Disease Control and Prevention (CDC) are updating the tables, replacing them with a sophisticated analytic software program. This program, the Interactive RadioEpidemiological Program (IREP)¹, models the dose-response relationship between ionizing radiation and 33 cancers using morbidity data from the same Japanese atomic bomb survivor cohort. In the case of thyroid cancer, radiation risk models are based on a pooled analysis of several international cohorts^{1a}.

(b) NIOSH will change the risk models in IREP, as needed, to reflect the radiation exposure and disease experiences of employees covered under EEOICPA, which differ from the experiences of the Japanese atomic bomb survivor cohort. Changes will be incorporated in a version of IREP named NIOSH-IREP, specifically designed for adjudication of claims under EEOICPA. Possible changes in IREP risk models include the following:

(1) Addition of risk models to IREP, as needed, for claims under EEOICPA

(e.g., malignant melanoma and other skin cancers)

(2) Modification of IREP risk models to incorporate radiation exposures unique to employees covered by EEOICPA (e.g., radon and low energy x rays from employer-required medical screening programs, adjustment of relative biological effectiveness distributions based on neutron energy).

(3) Modification of IREP risk models to incorporate new understanding of radiation-related cancer effects relevant to employees covered by EEOICPA (e.g., incorporation of inverse dose-rate relationship between high LET radiation exposures and cancer; adjustment of the low-dose effect reduction factor for acute exposures).

(4) Modification of IREP risk models to incorporate new understanding of the potential interaction between cancer risk associated with occupational exposures to chemical carcinogens and radiation-related cancer effects.

(5) Modification of IREP risk models to incorporate temporal, race and ethnicity-related differences in the frequency of certain cancers occurring generally among the U.S. population.

(6) Modifications of IREP to facilitate improved evaluation of the uncertainty distribution for the probability of causation for claims based on two or more primary cancers.

§ 81.11 Use of uncertainty analysis in NIOSH-IREP.

(a) EEOICPA requires use of the uncertainty associated with the probability of causation calculation, specifically requiring the use of the upper 99% confidence interval (credibility limit) estimate of the probability of causation estimate. As described in the NCI document,² uncertainty from several sources is incorporated into the probability of causation calculation performed by NIOSH-IREP. These sources include uncertainties in estimating: radiation dose incurred by the covered employee; the radiation dose-cancer relationship (statistical uncertainty in the specific cancer risk

¹NIOSH-IREP is available for public review on the NIOSH homepage at: www.cdc.gov/niosh/ocas/ocasirep/html.

^{1a}Ron E, Lubin JH, Shore RE, et al. "Thyroid cancer after exposure to external radiation: a pooled analysis of seven studies." *Radiat. Res.* 141:259–277, 1995.

²Draft Report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables, May 31, 2000, p. 17–18, p. 22–23.